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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,423	07/29/2003	Kiran K. Chada	69014-A/GJG	1805

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,423	CHADA ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-116* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method of identifying genes that are over-expressed in adipose tissue as compared to non-adipose tissue comprising differential gene expression, classified in class 435, subclass 6.

II. Claims 10-21, 31, 47-57, 67, 82-91, 101, drawn to a nucleic acid, a vector comprising the same, a host cell comprising the vector and a method of making a protein using said host cell, classified in class 435, subclass 69.1.

III. Claims 22-23, 58-59, 92-93, drawn to a polypeptide, classified in class 530, subclass 350.

IV. Claims 24, 60, 94, drawn to an antibody, classified in class 530, subclass 287.1.

V. Claims 25-26, 61-62, 95-96, as drawn to a method for treatment of a subject in need of enhance activity or expression of a polypeptide, classified in class 514, subclass 1.

VI. Claims 25-26, 61-62, 95-96, as drawn to a method for treatment of a subject in need of decreased activity or expression of a polypeptide, classified in class 514, subclass 1.

VII. Claims 27, 63, 97, as drawn to a method for diagnosing a susceptibility to diabetes or obesity in a subject comprising determining the presence or absence of a mutation in the nucleic acid encoding a protein, classified in class 435, subclass 7.1.

VIII. Claims 28, 32-44, 64, 68-80, 98,103-115, as drawn to a method for identifying compounds which antagonize or agonize a polypeptide comprising contacting a candidate compound with a cell expressing said polypeptide and measuring the binding, stimulation or inhibition by said compound to the polypeptide, classified in class 435, subclass 7.1.

IX. Claims 29, 46, 65, 81, 99, 116, as drawn to an agonist to a polypeptide, classified in class and subclass would depend on the structure of a compound.

X. Claims 30, 46, 66, 81, 100, 116, as drawn to an antagonist to a polypeptide, classified in class and subclass would depend on the structure of a compound.

XI. Claims 45, 102, 104-115, as drawn to a bioassay for identifying compounds which prevents adipose accumulation comprising exposing a eukaryotic cell that expresses a polypeptide to a compound and monitoring the cell to change in activity which is predictive of adipose accumulation, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, V, VI, VII, VIII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of identifying genes that are over-expressed in adipose tissue as compared to non-adipose tissue comprising differential gene expression (group I), the method for treatment of a subject in need of increased activity or expression of a polypeptide (group V), the method for treatment of a subject in need of decreased activity or expression of a polypeptide (group VI), the method for

diagnosing a susceptibility to diabetes or obesity in a subject comprising determining the presence or absence of a mutation in the nucleic acid encoding a protein (group VII) , the method for identifying compounds which antagonize or agonize a polypeptide comprising contacting a candidate compound with a cell expressing said polypeptide and measuring the binding, stimulation or inhibition by said compound to the polypeptide (group VIII), and the method for identifying compounds which prevents adipose accumulation comprising exposing a eukaryotic cell that expresses a polypeptide to a compound and monitoring the cell to change in activity which is predictive of adipose accumulation (group XI) are all unrelated as they comprise distinct steps and utilize different patient populations which demonstrates that each method has a different mode of operation. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I, V, VI, VII, VIII and XI are patentably distinct.

Inventions II, III, IV, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleic acids of Group II, the polypeptide of Group IIII, the antibody of Group IV, an agonist of Group IX and an antagonist of Groups X are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polynucleotide of Group II and the polypeptide of Group III are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of

Group II does not necessarily encode the polypeptide of Group III.

The polypeptide of Group III and the antibody of Group IV are patentably distinct for the following reasons: while the inventions of both Groups III and IV are polypeptides, in this instance, the polypeptide of Group III is a single chain molecule, whereas the polypeptide of Group IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Group III and the antibody of Group IV are structurally distinct molecules; any relationship between a polypeptide of Group III and an antibody of Group IV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide. In this case, the polypeptide of Group III is a large molecule which contains potentially hundreds of regions to which an antibody must bind, whereas the antibody of Group IV is defined in terms of its binding specificity to a polypeptide within the disclosed SEQ ID NO:. Thus, immunization with the polypeptide of Group III would result in the production of antibodies outside the scope of Group IV. Therefore, the polypeptide and antibody are patentably distinct.

The polynucleotide of Group II and the antibody of Group IV are patentably distinct for the following reasons: the antibody of Group IV includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of Group IV which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship

between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group II will not encode an antibody of Group IV, and an antibody of Group IV cannot be encoded by a polynucleotide of Group II. Therefore, the antibody and polynucleotide are patentably distinct.

The nucleic acids of Group II, the agonist of Group IX and the antagonist of Groups X are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Therefore, the polynucleotide of Group II is patentably distinct from Groups IX/X.

The polypeptide of Group III, the agonist of Group IX and the antagonist of Groups X are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Therefore, the polypeptide of Group III is patentably distinct from Groups IX/X.

The antibody of Group IV, the agonist of Group IX and the antagonist of Group X are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Therefore, the antibody of Group IV is patentably distinct from Groups IX/X.

The agonist of Group IX and the antagonist of Group X are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. A compound (agonist) of Group IX of undisclosed structure does

not necessarily belong to the compounds (antagonists) of Group X.

Inventions II and V/VII/VIII/XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Inventions III and V/VII/XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Inventions IX and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a compound of unknown structure of Group IX can be used to make an antibody, if said compound is a polypeptide, for example.

Inventions X and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a compound of unknown structure of Group X can be used to

make an antibody, if said compound is a polypeptide, for example.

Invention II and I/VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The methods of Groups I/VI do not use a product of Group II.

Invention III and I/VI/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The methods of Groups I/VI/VIII do not use a product of Group III.

Invention IV and I/V/VI/VII/VIII /XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The methods of Groups I/V/VI/VII/VIII /XI do not use a product of Group IV.

Invention IX and I/VI/VII/VIII /XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The methods of Groups I/VI/VII/VIII /XI do not use a product of Group IX.

Invention X and I/V/VII/VIII /XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The methods of Groups I/V/VII/VIII /XI do not use a product of Group X.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further Restriction Requirement
Groups III/IV/VIII/XI

If Group III, IV, VIII or XI is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions Groups III, IV, VIII or XI pertain to a number of polypeptide sequences encoded by a nucleic acid listed in claims 22, 23, 25-28, 33-35, 45, 47 and many others (i.e., SEQ ID NOs: 1-279) or polypeptides of SEQ ID NOs: 603 and 778.

Each of the claimed polypeptide sequences are composed of amino acid units and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching two claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. **Therefore, Applicant must choose 1 sequence from the group against which the search should be performed.**

Groups II/VII

If Group II or VII is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions of Groups II and VII pertains to a number of polynucleotide sequences listed in claims 11-15, 47, 49, 50 and many others (i.e., polynucleotides of SEQ ID NOs: 1-279) or a polynucleotide that encodes a polypeptide of SEQ ID NO: 603 or 778.

Each of the claimed nucleic acid sequences are composed of different purine and pyrimidine units and are structurally distinct molecules. Each sequence or gene requires a unique separate search of the prior art. Searching two claimed sequences or genes would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. **Therefore, Applicant must choose 1 sequence or gene from the group against which the search should be performed.**

Species Election

This application contains claims directed to the following patentably distinct species:

Claim 27 is drawn to a number of patentably distinct species (diseases), e.g., obesity or diabetes.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species and that each species is different from

other species in its structure and function relationship such as obesity is very different than diabetes. In addition, these species are not obvious variants of each other based on the current record.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 28 and 64 are drawn to a number of patentably distinct species (observing functional response), e.g., binding, stimulation or inhibition.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species and that each species is different from other species in its structure and function relationship such as observing/determining binding between a peptide and compound is very different than observing stimulation or inhibition of a polypeptide in response to a compound. In addition, these species are not obvious variants of each other based on the current record.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another

species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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21 August 2007
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/Robert S. Landsman/
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